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6201 South Freeway
Fort Worth Texas 76134-2099

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,889,052

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,889,052, which claims the human drug product TRAVATAN™ (travoprost), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 486 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 486 days.

The period of extension has been calculated using the Food and Drug Administation determination of the length of the regulatory review period published in the Federal Register of February 28, 2002 (67 Fed. Reg. 9302). Under 35 U.S.C. § 156(c):

Period of Extension = 1/2 (Testing Phase) + Approval Phase
= 1/2 (1441 - 975) + 253
= 486 days

Since the regulatory review period began July 28, 1996, before the patent issued (March 30, 1999), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From July 28, 1996 to March 30, 1999 is 975 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor the 14 year limitation of 35 U.S.C. § 156(c)(3) operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,889,052
Granted:	March 30, 1999
Original Expiration Date[1]:	August 3, 2013
Applicant:	Peter G. Klimko, et al.

[1]Subject to the provisions of 35 U.S.C. § 41(b).

Owner of Record:	Alcon Manufacturing, Ltd.
Title:	Use of Cloprostenol and Fluprostenol Analogues to Treat Glaucoma and Ocular Hypertension
Classification:	514/530
Product Trade Name:	TRAVATAN™ (travoprost)
Term Extended:	486 days
Expiration Date:	December 2, 2014

Any correspondence with respect to this matter should be addressed as follows:

By mail: Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 872-9411

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RE: TRAVATAN™ (travoprost)
FDA Docket No.: 01E-0362